

Working group - „Interdisciplinary unit for early clinical trials and studies“

Networking of the Early Clinical Trial Units (ECTUs) at the 6 Bavarian University Hospitals for easier access for patients to participate in innovative treatment options and for sponsors to potentially collaborate.

Activities & Achievements

The development of new drugs and therapies is based on innovative preclinical research and clinical testing. The studies in early clinical phases of drug development can only be realized in highly experienced trial units, so called "early clinical trial units (ECTU) to guarantee patients' safety and handle complex trial logistics. In order to optimize access to early clinical trials for patients and referring physicians, networking of the ECTUs located at all 6 university sites of the BZKF is necessary and allows for joint professionalization and synergistic collaboration. Collaboration takes place on several levels:

One of the overarching structural elements of the ECTU network is the **Strategic Board**. Members of all 6 ECTUs, network coordinators, study nurses as well as representatives of the respective legal departments meet every 4 weeks (Jour Fixe) to discuss new study projects and define strategic concepts.

A joint **ECTU Tumor Board** is held every two weeks, with at least one

representative from each ECTU participating. Patients can be discussed to identify potential appropriate trials and treatment slots for phase I trials can be filled promptly.

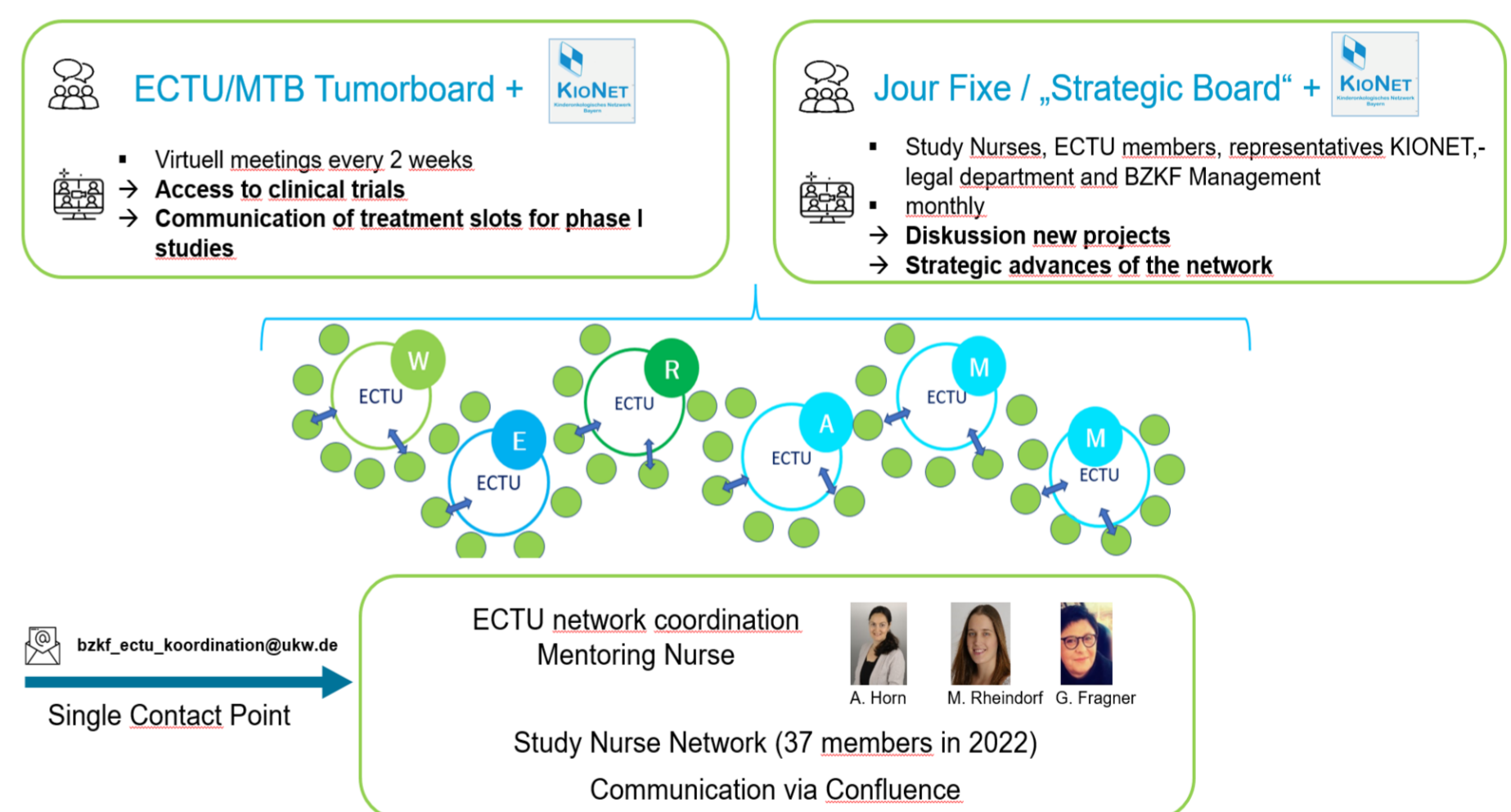
Members of the newly established **Study Nurse Network** (37 members in 2022) meet virtually every 8 weeks, face-to-face meetings take place once a year together with an additional information exchange through hospitations. A **common SOP portal** was established through this collaboration and advanced through 2-weekly meetings - always with the support of an **ECTU Mentoring Nurse**.

A **single contact point** has been established for the network for easier access and more efficient contacting and reliable information exchange.

In November 2021 the already well established pediatric trials network **KIONET joined the ECTU network** and respective members participate in the ECTU board to discuss experimental treatment options for children with malignant diseases. **First inquiries from sponsors,** pipeline introductions and the initiation of the **first joint phase I FIH trial** demonstrate nicely, that the ECTU network works successfully.

A **joint BZKF study contract** has been drafted and fundamentally supports this goal.

In the future, this will be further optimized by a joint Internet presence and presentation of the ECTUs as well as a strategically clear action algorithm for contact inquiries.



Visions & Future Goals

- » We will develop a common trials portfolio to address the needs of our patients
- » We will ensure fair and equal access to innovation, even in underserved regions
- » We will bundle expertise and use synergies to speed-up trial processes
- » We will raise awareness of clinical trials to facilitate trial recruitment and enforce the recruitment potential of the network

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